



2400 West Lloyd Expressway Evansville, IN 47721-0001 812-429-5000

September 17, 2004

20 2004

Susan Walker, M.D.
Office of Nutritional Products, Labeling, and Dietary Supplements (HFS-810)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

Re: Notification of Statements of Nutritional Support

Dear Dr. Walker,

Pursuant to 21CFR 101.93, this letter and the attached two copies are submitted by Mead Johnson & Company as a notification that a dietary supplement with labels bearing statements in accordance with section 406(r)(6) of the Federal Food, Drug, and Cosmetic Act has been first marketed within the last 30 days, as follows:

Name and address of distributor

Mead Johnson & Company
2400 West Lloyd Expressway
Evansville, IN 47721

Statements

"Expecta LIPIL DHA supplement supports your baby's brain and eye development during pregnancy and while breastfeeding"

"New Expecta LIPIL DHA supplement helps you support your baby's brain and eye development"

"DHA (docosahexaenoic acid), a special omega-3 fatty acid clinically shown to support brain and eye development"

"During this critical period of growth [in utero and breastfeeding], DHA can be an important factor – especially for brain, visual and nervous system development. "

"Expecta LIPIL DHA supplement increases blood levels of DHA for yourself and for your baby, which may help to support development of your baby's brain and eyes"

Dietary ingredient

DHA (docosahexaenoic acid)

97S 0162

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A Bristol-Myers Squibb Company



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Product

ExpectaTM LIPIL[®] DHA supplement

The undersigned certifies that the information contained in this notice is complete and accurate and that Mead Johnson & Company has substantiation that the statements are truthful and not misleading.

Sincerely,

A handwritten signature in black ink, appearing to read "Matias Diez".

Matias Diez
Manager, Regulatory Affairs
Mead Johnson & Company

CC: Thomas L Ferguson
Director, Regulatory Affairs
Mead Johnson & Company



A Bristol-Myers Squibb Company